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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte HALIL I. KARABEY, ANNA G. PRESTEZOG, MICHAEL S. MIRIZZI, BRIAN FARLEY, JOHN W. RODRIGUEZ, and RUSSELL B. THOMPSON

Appeal 2014-009997
Application 13/556,260
Technology Center 3700

Before ANNETTE R. REIMERS, JILL D. HILL, and LISA M. GUIJT, *Administrative Patent Judges*.

GUIJT, *Administrative Patent Judge*.

DECISION ON REQUEST FOR REHEARING

Appellants filed a Request for Rehearing, dated February 28, 2017, in response to the Decision mailed January 3, 2017 (the "Decision"). In the Decision, the Board affirmed the Examiner's rejection of claims 1–6, 9–15, 18–28, and 30–32, and designated the affirmance as a new ground of rejection.

We do not modify the Decision.

ANALYSIS

In the Final Office Action[1] from which appeal was taken, the Examiner relied on embodiments in Callister which disclose that the fibrous member 15 or fibrous mass 42 forms a complex along with tissue ingrowth or is permeable to allow for tissue ingrowth, for occluding the reproductive lumen, and therefore, we were persuaded by Appellants' argument that to determine that such embodiments would work for their intended purposes (i.e., occlusion) if the fibrous members were modified to bioabsorb would be speculative. *See* Decision 4–6. However, we determined that because Callister also discloses an embodiment wherein the presence of the fibrous member is optional and supplemental to a *functioning* occlusion device, Appellants' argument that a biobsorbable fibrous member would cause the device not to work for its intended purpose was not persuasive. *See id.* at 6–7. Because we relied on an embodiment disclosed in Callister that was not relied on by the Examiner, we designated the affirmance as a new ground of rejection.

Requests for Rehearing are limited to matters misapprehended or overlooked by the Board in rendering the original decision. 37 C.F.R. § 41.52. Appellants argue that

> the Board misapprehended or overlooked that the apparatus for occluding a hollow anatomical structure of claim 1 includes, *inter alia*, "radially bulked fibers [that] are self-expanding, such that the implant is . . . self-expandable in the radial direction." . . . In the new ground of rejection, the Board relied on a different embodiment of Callister's occlusive device than the embodiment of Callister's occlusive device relied on by the Examiner. However, the Board misapprehended or overlooked that the

[1] The Final Office Action dated March 14, 2014 ("Final Act.").

> Examiner's assertion . . . that Callister in view of Galdonik allegedly described radially bulked fibers that are self-expanding was based on the embodiment of Callister relied on by the Examiner. Accordingly, the Board failed to establish that the apparatus for occluding a hollow anatomical structure of claim 1, which includes radially bulked fibers that are self-expanding, such that the implant is self-expandable in the radial direction, would have been obvious over Callister in view of Gladonik based on the embodiment of Callister relied on by the Board.

Request 3. Thus, Appellants do not argue that the Examiner's proposed modification of the alternative embodiment in Callister relied on by the Board would fail to result in a device that works for its intended purpose. Rather, we understand that Appellants are arguing that (i) there is no support in Callister for a finding of self-expanding fibers as applied to the embodiment in Callister relied on by the Board; and (ii) there is no support in Callister or Galdonik, alone or in combination, for a finding that self-expanding fibers also *results in* self-expansion of the implant in a radial direction, as applied to the embodiment in Callister relied on by the Board, which Appellants contend is a requirement of independent claims 1 and 24.

Regarding whether the record supports a finding of self-expanding fibers, in the Final Office Action, the Examiner determined that "**Callister** discloses the fibers 'expand' across the lumen of the vessel." Final Act. 5 (citing Callister ¶ 41). Although this finding was not challenged by Appellants during the appeal, Appellants now contend that "Callister fails to disclose or suggest that the fibrous body is self-expanding." Request 4; *see* Appeal Br. 3–12; Reply Br. 2–6. Notwithstanding, the Examiner alternatively relies on Galdonik for teaching "similar fibers that self-expand across a vessel lumen, by becoming relatively shorter and relatively thicker," and reasons that it would have been obvious "to modify the fibers of

Callister with the self-expanding nature as taught by **Galdonik** . . . to ensure the expansion across the vessel as desired by **Callister**." Final Act. 5 (citing Galdonik ¶ 168; Callister ¶¶ 41, 50).[2] The Board implicitly relied on these findings when designating the affirmance as a new ground. Decision 9 ("We designate our affirmance as a new ground of rejection . . . to the extent we have relied on passages from the prior art which were not relited upon by the Examiner.") Appellants also did not present any arguments during the appeal proceedings that these findings by the Examiner regarding Galdonik's disclosure of self-expanding fibers contained errors (*see* Appeal Br. 3–12; Reply Br. 2–6), nor do Appellants challenge this finding in the Request (*see* Request 3–9). Instead, Appellants argue in the Request that Galdonik does not disclose that such self-expanding fibers result in expansion of the implant. *See e.g.*, *id.* at 8 ("the cited embodiments of Galdonik do not describe or suggest self-expansion of a fibrous body that would necessarily result in the expansion of an implant including the fibrous body. Instead, . . . Galdonik merely describes that a 'surface capillary fiber [SCF] has a configuration to fill a lumen . . . .'").

Thus, the Board did not misapprehend or overlook that the apparatus for occluding a hollow anatomical structure of claim 1 includes, *inter alia*, fibers that are self-expanding, as argued by Appellants. Rather, the Examiner's reasoning to modify Callister's fibers to be self-expanding, with respect to either the embodiment relied on by the Examiner or the

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[2] *See also* Galdonik ¶ 131 ("device **270** comprises an expanding polymer . . . for example, a fiber . . . that has shape memory upon heating to body temperature" such that "released fibers resume their memory shape at the expanded configuration to fill the vessel.").

embodiment relied on by the Board, is equally supported by Galdonik's disclosure to use self-expanding fibers to fill the vessel. *See* Final Act. 5 ("**Galdonik** teaches similar fibers that self-expand across a vessel lumen," and therefore, "it would have been obvious . . . to modify the fibers of **Callister** with the self-expanding nature as taught by **Galdonik** . . . to ensure expansion across the vessel as desired by **Callister**.")

Regarding Appellants' second argument, Appellants contend that "the Board overlooked the fact that Callister does not disclose or even suggest that its described fibrous body, when disposed within the inner lumen 65 of the occluding component 61, is 'self-expanding, such that the implant is . . . self-expandable in the radial direction . . . .'" Request 4; *see* Callister, Fig. 15. In other words, Appellants contend that "the Board has not cited to any factual basis to support an assertion that a person having ordinary skill in the art would have understood self-expansion of Callister's fibrous body 42 to have resulted in expansion of the occluding device 60 relied on by the Board. *Id.* at 5.

Independent claim 1 recites, in relevant part, "an implant . . . comprising a fibrous mass of . . . fibers . . . ; wherein the . . . fibers are self-expanding, such that the implant is delivered in a compressed, low-profile state . . . , and self-expandable in the radial direction . . . ." Appeal Br. 13 (Claims App.). We determine that claim 1 may be read to mean that (i) the *fibers are* self-expanding . . . and *self-expandable* in the radial direction; or (ii) the fibers are self-expanding, such that the *implant is . . . self-expandable* in a radial direction. Notwithstanding, we determine, for the reason stated *infra*, that claim 1 does not require the self-expansion of the fibers *to cause* the implant to *self*-expand in the radial direction, as argued by Appellants.

Accordingly, Appellants' argument is not commensurate with the scope of the claim language.

Adopting Appellants' claim construction, wherein the fibers are self-expanding, such that the implant is *both* deliverable in a compressed state and self-expandable in the radial direction, Callister discloses that helical coils 62 and 64 are "self-expandable for deployment within a patient's body lumen," and according to the Examiner's proposed modification, the fibrous body (not shown in the embodiment of Figure 15) is also self-expanding, in view of Galdonik. *See* Callister ¶ 52; Final Act. 5. Thus, the ability of the fibers themselves to self-expand within the implant *allows* the implant to be deliverable in a compressed state, because the fibrous mass within the implant is capable of also being in an unexpanded state upon delivery, and the ability of the fibers themselves to self-expand within the implant *allows* the implant to be self-expandable in the radial direction, because if the fibers were not self-expanding, then the implant would have to be delivered in an expanded state to accommodate the expanded fibers within the implant. Moreover, the claim requires the implant to be *self*-expanding—not expanded by the expansion of fibers. In sum, claim 1, as written, does not require the self-expansion of the fibers *to cause* the implant to expand (or more accurately, to *self*-expand).

The same analysis is equally applicable to the language of independent claim 24, which recites, in relevant part, "a scaffold . . . at least a section of the scaffold comprising . . . fibers . . . ; wherein the . . . fibers are self-expanding, such that the scaffold is deliverable in a compressed, low-profile state . . . , and self-expandable in the radial direction at a treatment site in the HAS." *Id.* at 14–15 (Claims App.).

For these reasons, we determine that it is immaterial as to whether "Callister fails to disclose or suggest that . . . the fibrous body has any impact on Callister's occluding device 60 itself," as argued by Appellants. Request 4.

Appellants also argue that "neither the Board nor the Examiner has established that a person having ordinary skill in the art would have understood the straightened initial configuration of Galdonik's SCF fibers to have been radially-bulked fibers, as recited by claim 1," and further, that "Galdonik's fibers that are 'stretched straight' are not radially-bulked." Request 8. Appellants are presenting this argument for the first time on appeal in the Request. It is inappropriate, however, for Appellants to discuss for the first time in a Request for Rehearing matters that could have been raised in the Appeal Brief. *See Ex part Borden*, 93 USPQ2d 1473, 1474 (BPAI 2010) (informative decision). Here, we do not have the benefit of the Examiner's position on this question. Therefore, we decline to consider this new argument.

DECISION

We grant the Request to the extent that we have reconsidered the record. The Request for Rehearing is denied.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). *See* 37 C.F.R. § 1.136(a)(1)(iv).

REHEARING DENIED